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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,522	11/02/2001	Srinivas Uppugunduri	6482	5896

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EXAMINER
KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/986,522	Applicant(s) UPPUGUNDURI, SRINIVAS	
	Examiner Brian S Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☒ Claim(s) *5-7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 November 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Preliminary Amendment

1. Acknowledgment is made of applicant's submitting of preliminary amendment on November 02, 2001. Claims 5-6 have been amended. Claims 1-7 are currently pending for the prosecution on the merits.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in PCT/SE00/00827 on May 02, 2000. It is noted, however, that applicant has not filed a certified copy of the SWEDEN 9901615-6 filed on May 5, 1999 application as required by 35 U.S.C. 119(b).

Drawings

3. The drawings filed November 02, 2001 are objected to by the Draftsperson under 37 CFR 1.84 or 1.152. Applicant is requested to notice the box 10 and 12 made by the Draftsperson. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Information Disclosure Statement

4. Acknowledgement is made of applicant's submitting of the information disclosure statement (IDS) on December 7, 2001. Accordingly, the information disclosure statement (IDS) has been considered by the examiner.

Specification

5. The specification is objected to because of misspelling of word "inflammary bowl disease (IBD)". It is suggested to change it to "inflammatory bowl disease (IBD".

Claims Objection

6. Claim 7 appears to be missing "The" before "Method according to claim 6...".

Claim Rejections - 35 USC § 101

7. Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 provide for the use of 4-thiuridine, isomaltitol, and/or uridine, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it

merely recites a use without any active, positive steps delimiting how this use is actually practiced.

9. Claims 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential step, such omission amounting to a gap between the steps. See MPEP § 2172.01. It appears essential in view of the instant specification that the claimed composition is administered to a subject in need of such treatment (i.e., L-cells transfected with E-selectin) to exert the claimed pharmacological effect. However, the claims fail to recite such essential step and are consequently unclear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Borstel et al. (US 5583117).

The claims appear to be directed to a method for treatment of acute or chronic inflammations comprising administering a therapeutically effective amount of one or more active compound(s) selected from the group consisting of 4-thiouridine, isomaltitol and uridine to a subject in need of such treatment, with the exception of the use of uridine in the treatment of inflammatory conditions caused by a bacterial infection. Further limitations include 4-thiouridine as the therapeutically effective compound (claim 2); uridine as the therapeutically effective compound (claim 4); the specific dosage of the active ingredient(s) in 1 to 100mg per kg body weight (claim 5); and the specific serum concentration level of the active ingredient(s) in 0.1 to 100mM (claim 7).

The instant specification defines that major inflammatory conditions where the present compounds find use is in asthmatic conditions, Crohn's disese, ulcerous colitis, reperfusion injury, auto-immune diseases, inflammatory bowl disease (IBD), arteriosclerosis, restenosis, cancer, coronary heart disease, diabetes, cancer metastasis, rhematoidal diseases, dermatological diseases, such as psoriasis, seborrhea, burn injury and graft rejection (~~column~~ page 6, line 34 thru ~~column~~ page 7, line 4).

Von Borstel teaches or suggests the method for treating pathological conditions including diabetes and coronary arteriosclerosis by delivering exogenonous uridine to the tissue of an animal comprising the administration of acylated uridine (column 15, line 65 thru column 16, line 7; column 17, lines 16; column 18, lines 34-49). The reference expressly teaches that the presence of uridine is important to the amelioration of a variety of physiological and pathological conditions, and the acylated uridine is more potent in treating the pathological conditions such as diabetes and coronary arteriosclerosis (column 8, lines 54-59; column 14, line 63 thru column 18, line 67; Examples I-II). The

reference also teaches or suggests that the dosage of acyl derivatives of uridine is preferably in doses equivalent to 0.5 to 3 grams of uridine are administered daily (column 17, lines 30-35; column 18, lines 22-24 and lines 46-47).

The claimed invention differs from the reference by (i) the use of uridine or 4-thiouridine, (ii) the specific dosage of uridine and (iii) the specific serum concentration of the active compound such as uridine.

One having ordinary skill in the art would have known in view of von Borstel that acylated uridine is readily available as uridine in the body and uridine is an active agent utilized in the treatment of diabetes and coronary arteriosclerosis. Furthermore, one having ordinary skill in the art would have expected that exogenous uridine is useful in treating acute or chronic inflammations such as diabetes and coronary arteriosclerosis. One having ordinary skill in the art would have readily understood that the administration of either exogenous uridine or uridine in the acylated form would have similar therapeutic utility in treating acute or chronic inflammations such as diabetes and coronary arteriosclerosis.

Although the reference is silent about the use of 4-thiouridine, one having ordinary skill in the art would have expected that uridine derivatives such as 4-thiouridine would not significantly alter the analogous properties of the compound of the reference due to close structural similarity of the compounds, absent evidence to the contrary.

Although the reference does not specifically disclose the claimed dosage range of the active compounds or the claimed serum concentration of the active compounds, those ordinary skill in the art will readily optimize effective dosages and concurrent serum concentration as determined by good medical practice and the clinical condition of the

individual patient. Regardless of the manner of administration, the specific dose may be calculated according to body weight, body surface area or organ size. Further refinement of the calculations necessary to determine the appropriate dosage for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed in von Borstel.

Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-2, 4-7 are properly rejected under 35 U.S.C. 103.

Conclusion

11. No Claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600